Knowledge Acquisition Session Report
Lombardi Cancer Center – Georgetown Univ Hospital

KA Session Date: Sept 23, 1999 **Session Time:** 11:00 a.m.

Session Topic: Clinical Trial Data Management

Knowledge Analyst: Jennifer Brush, ScenPro, Inc.

Organization: Clinical Research Management Office, Lombardi Cancer Center

Session Location: CRMO, LCC

Type of Session:

_____ Interview _____ Task Analysis _____ Scenario Analysis
_____ Concept Analysis _____ Observation __X__ Structured Interview
_____ Other:

Documentation:

- Knowledge Acquisition Session Report
- Case Report Forms – LCC Metastic Breast Cancer

General Topic Area

Clinical Trial Data Collection and Management

Session Goals

- Obtain an understanding of the responsibilities and day to day tasks of the Supervisor of Data Management
- Identify primary differences between clinical trial data collection and monitoring for NCI-sponsored, pharmaceutical company-sponsored, and Lombardi-sponsored trials.

Report Summary

Ms. Jean White is the Supervisor of Data Management in the Clinical Research Management Office, Lombardi Cancer Center at Georgetown University Medical Center, Washington, DC. Ms. White has over 12 years of experience in clinical trial data management. Her primary tasks as Supervisor of Data Management include: overseeing the activities of the eleven Data Managers at LCC, ensuring that clinical trial data is recorded in a timely and accurate manner, and participating in clinical trial monitoring and regulatory visits. Her expertise in the area of clinical trial data management allows her to provided valuable information for this project.

Clinical Trial Data Collection
Clinical trial data collection at Lombardi, centers around the patient medical record. One of Jean's tasks is to ensure that the patient medical record includes all relevant medical and clinical trial information.

Patient Medical Record
Patients enrolled in a clinical trial at the Lombardi Cancer Center have a medical record which is composed of three sections:

1) **Medical Record Chart**➔ kept in Medical Records Office
    a. Progress notes
    b. Consent form
    c. Test results
    d. Lab results
    e. Patient Exams
2) **Research Chart** ➔ Maintained by Data Managers
    a. Case Report Forms
3) **Inpatient Chart** (if the subject is a patient AT Georgetown) ➔ kept in Inpatient Office (basement)
    (note: In order to obtain a copy of the Inpatient record(s), LCC staff (i.e. Data Manager) must tell them what info is needed, they make copies of that information, then forward you the copies.)

One of the most time consuming activities for Jean and her Data Management staff is tracking down patient medical records. Patients may visit different clinics throughout the Georgetown University Medical Center campus. This information can be found on the 'Patient Flow Sheet' in their medical record. Their patient charts (medical record) is routed to each scheduled location. Locating the patient medical record so that it is on-hand when a patient makes a visit to the Lombardi Cancer Center is a time-consuming task.

Clinical Trial Data Reporting
A **Case Report Form** (CRF) is the set of documents on which patient medical and trial data is recorded (copies of the CRFs become a part of a patients official medical record). The CRF is a mechanism for distributing clinical trial-specific data to various sponsoring organizations.

Clinical Trials at Lombardi may be sponsored by the following organizations:

- A pharmaceutical company (or Drug Sponsor)
- The National Cancer Institute (NCI)
- Lombardi Cancer Center (Internal Clinical Trial)

Pharmaceutical companies provide Case Report Forms to Lombardi for each pharmaceutical-sponsored trials. Lombardi CRMO staff generate CRF's for NCI-sponsored trials. These internally-generated CRFs are created based on the data requirements for individual clinical trial protocols. CRMO staff also create CRF's for any internal Lombardi-sponsored trials.

These three types of Case Report Forms are used to record similar clinical trial data. However, CRFs from pharmaceutical companies may have gaps or missing pieces in their data collection requirements.

> For Example, a pharmaceutical company CRF may have an area for the recording of a standard Patient Exam (PE). Their CRF may not include an area in which to record the Temperature of the patient. Lombardi staff, who have a significant amount of experience with clinical trial data collection, note the 'missing' data field and ensure that the information is collected anyway.

Data Managers are responsible for transferring patient medical data onto the Case Report Forms. Jean's responsibility, as Supervisor of Data Management, is to ensure that the Case Report Forms are accurate, complete, and are filled out in a timely manner. If information is missing or incomplete, and the Data Manager has been unable to track down the information, then Jean assists with locating the missing data.

Clinical Trial Data Management
One of Jean's tasks is to ensure that, for each patient scheduled for a visit that afternoon, their patient chart (or medical record) is on-hand. Jean receives a copy of the patient visit schedule each morning. The schedule shows the patient name and what time they are scheduled to arrive that same afternoon (*is there more info on this schedule*?).

It is up to individual Data Managers to make sure a patient's medical record is on hand for their visit. If the Data Manager has trouble locating or retrieving the medical record, Jean will step in as Supervisor and assist.

Clinical Trial Data Monitoring
Lombardi Cancer Center conducts cancer clinical trials sponsored by pharmaceutical companies, the National Cancer Institute, and Lombardi itself Monitoring clinical trial data collection and reporting processes is an important part of conducting clinical trials.

Pharmaceutical-Sponsored Trial Monitoring
Pharmaceutical-sponsored trial data collection is subject to review every 6 weeks (on average). A representative from the pharmaceutical company, usually referred to as a Monitor, contacts the LCC to inform them of a pending visit. According to Jean, Monitors are very helpful in providing specific direction to LCC staff about upcoming reviews. Lombardi staff are usually aware of what patient data will be reviewed (usually 6 individual patients are selected for review for each clinical trial), what specific forms will be reviewed, and what kind of information format Monitors are looking for.

Monitors take a copy of the patient CRF back to the pharmaceutical company with them for review. If they require additional patient information, or have a question about the patient data on the form, the Monitor faxes a 'Query' back to the LCC.

LCC staff address the questions in the 'Query' and fax a response back to the pharmaceutical company Monitor. It is important that Lombardi staff maintain a good working relationship with pharmaceutical Monitors.

NCI-Sponsored Trial Monitoring
NCI sponsored clinical trial data collection is monitored by Theradex. There are normally two annual visits from Theradex: 1) NCI site visit, and 2) an annual monitoring visit. (*what is the difference between these two visits?*). This year, these visits will be combined in one large meeting.

NCI monitoring representatives look at the following information:

- Drug Accountability Log from the Pharmacy
- Study Reports *(from the PI?)*
- Manuscripts *(from the PI?)*
- Patient ID
- Date of progression on drugs
- Patient Research Chart
- Patient Medical Chart
- Patient NCI-outpatient Chart
- All labs/x-rays/test data

Lombardi-Sponsored Trial Monitoring
Lombardi-sponsored clinical trial data collection is monitored by the Director of the Clinical Research Management Office, Jan Hewitt. Jean also assists with this data monitoring task.

Wish List

- Would like to receive patient schedule on the day BEFORE the scheduled patient visit, in order to have sufficient time to prepare & locate patient charts
- Would like to have patient medical records available electronically
- Would like Data Managers to focus primarily on data entry/management